From: Nancy Fitz
To: Joanne Durand

Subject: Re: Follow up to the Refillable/Non-Refillable Label

Date: 09/16/2011 04:21 PM

Joanne,

The written version of the policy we discussed this morning is in the following Q&As. Admittedly, these Q&As aren't quite as straightforward as how we discussed it this morning, but the key point is in the first paragraph in Answer 1:

"...However, it may be acceptable for a pesticide product's label to have Container Handling/Container Disposal instructions for multiple container types in which that product can be sold, provided that the presentation of the alternative instructions is sufficiently clear that it will be read and understood by the end user under customary conditions of purchase and use, and not detract from other label provisions. If an end user cannot tell which set of Container Handling/Container Disposal instructions to follow, the pesticide would be misbranded."

Question 1: Is it acceptable to include Container Handling/Container Disposal instructions for all of the container types in which a pesticide can be sold on the product label?

Answer 1: EPA believes that is preferable for the label that appears on or is securely attached to the immediate container to only have instructions for that specific container. However, it may be acceptable for a pesticide product's label to have Container Handling/Container Disposal instructions for multiple container types in which that product can be sold, provided that the presentation of the alternative instructions is sufficiently clear that it will be read and understood by the end user under customary conditions of purchase and use, and not detract from other label provisions. If an end user cannot tell which set of Container Handling/Container Disposal instructions to follow, the pesticide would be misbranded.

Previous guidance (Container-Containment FAQ #12 - see below) advised that registrants could submit a single label with alternative storage and disposal statements for different container types and sizes. This guidance stated that "A label submitted for EPA review that bears alternative statements must indicate the circumstances in which each statement would appear on a final container label. ... The proposed labels will be reviewed by the appropriate Product Manager or the Notification Team and approved if acceptable."

Some current labels with alternative handling/disposal statements were approved under the assumption that end users generally understood that 1- and 2.5-gallon containers are not ordinarily intended to be refillable, and thus did not specifically identify the containers as non-refillable and did not specifically exclude 1- and 2.5-gallon containers from the refillable container instructions. However, in order to facilitate the use of 1- and 2.5-gallon refillable containers in the future, EPA intends to ask registrants to revise these labels to clarify whether containers are refillable or non-refillable when other label changes are proposed. During its review of future label amendments, EPA will also look for situations where multiple handling/disposal instructions might appear to apply to the same container and ask for clarification of those instructions.

Question 2: A registrant sells a pesticide in 275-gallon nonrefillable containers and 275-gallon refillable containers. Not knowing which type of container the label will be applied to, can the registrant print both refillable container and nonrefillable containers on the same label and use a separate sticker on the container designating the container as refillable or nonrefillable?

Answer 2: As discussed in the previous question, a pesticide product's label can have Container Handling/Container Disposal instructions for all container types in which that product can be sold. Since this container is not a 1- or 2.5-gallon container, the label would have to clearly identify the container as nonrefillable or refillable as well as the net contents.

"Label" is defined in section 2(p) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as "The term 'label' means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers." So, the container sticker is part of the label and can be used to help the user identify the appropriate Container Handling/Container Disposal Instructions. EPA recommends including a reference statement in the storage and disposal section of the label to make it very clear to the users how they can identify the container as nonrefillable or refillable. For example, a statement such as "See the sticker on the container to determine if it nonrefillable or refillable." could be included as part of the Container Disposal/Handling instructions (and above the subheadings).

For reference: existing FAQ #12 on the web site:

Question: How should a product that is packaged in multiple container types and/or sizes comply with the container and containment labeling requirements in 40 CFR § 156.140 - § 156.159 and described in PR Notice 2007-4?

Answer: Each pesticide product must bear storage and disposal statements appropriate for its container. The registrant may submit separate labels for each container type and/or size, or may submit a single label with alternative storage and disposal statements. A label submitted for EPA review that bears alternative statements must indicate the circumstances in which each statement would appear on a final container label. For example, a registrant could provide that circumstance information in italics or brackets. The proposed labels will be reviewed by the appropriate Product Manager or the Notification Team and approved if acceptable.

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"Joanne Durand" ---09/16/2011 03:33:33 PM---Hi Nancy.

From: "Joanne Durand" < joanne@aginfodata.com>

To: Nancy Fitz/DC/USEPA/US@EPA

Date: 09/16/2011 03:33 PM

Subject: Follow up to the Refillable/Non-Refillable Label

Hi Nancy,

I need a huge favor please...I would be forever grateful (as I always am).

This morning we talked about the circumstances in which a separate Refillable/Non-Refillable label may not be necessary; the conclusion was, that if the Pesticide label isn't clear then a separate label is necessary. And, a pesticide label may have multiple instructions re: refillable/non-refillable (depending on the size of the container it's be transferred into) and may not be clear then would need a separate label; the caveat was if it is clear...then a separate label is NOT required. So, all that being said, what I really need is for you to put that in writing to me in an e-mail so that I can speak intelligently to customers and potential customers and so that I can "use" it when speaking to the customer who had the initial question...and send it along to them if necessary.

Thank you from the bottom of my label and seal selling heart!

Joanne Durand

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